



Provincial Health Services Authority

For the Patient: GUBAVE

Other Names: Maintenance Therapy of Locally Advanced or Metastatic Urothelial Carcinoma using Avelumab

GU = GenitoUrinary
AVE = AVElumab

ABOUT THIS MEDICATION

What is this drug used for?

- Avelumab (a vel' ue mab) is a drug that is used to treat bladder cancer.

How does this drug work?

- Avelumab is a type of therapy called immunotherapy. It is an antibody designed to help your own body's immune system target cancer cells to stop them from growing.

INTENDED BENEFITS

- This treatment is being given to slow down the growth of your cancer cells in your body. This treatment can help to control some of the symptoms that cancer may be causing and may delay or prevent new symptoms from starting.

TREATMENT SUMMARY

How is this drug given?

- Avelumab will be given as an infusion (a drip) into a vein (intravenously) over a period of 60 minutes.
- You will be treated with avelumab once every 2 weeks. This 2-week period is called a "cycle". The cycle is repeated and the number of cycles will depend on your treatment plan.

What will happen while I am being treated?

- A blood test (lab work) and other tests are done before starting each treatment cycle.
- Treatment may be interrupted based on your test results and/or side effects.

INSTRUCTIONS FOR THE PATIENT

It is very important to report side effects immediately to your doctor. Do not manage side effects at home without speaking with your doctor. Be aware that symptoms may be delayed and can develop months after your last dose. If other doctors are involved in your care it is important they know you are on these treatments and the autoimmune side effects they can cause.

What other drugs or foods can interact with avelumab?

- Other drugs may interact with avelumab. Check with your doctor or pharmacist before you start or stop taking any other drugs including all prescription and non-prescription medicines, steroids or other medicines that lower your immune response, vitamins and herbal supplements.
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of avelumab.

Other important things to know:

- **Before you are given avelumab**, talk to your doctor if you:
 - have an active condition where your immune system attacks your body (autoimmune disease), such as ulcerative colitis, Crohn's disease, rheumatoid arthritis, multiple sclerosis, lupus or sarcoidosis.
 - take other medicines that make your immune system weak. Examples of these may include steroids, such as prednisone or dexamethasone.
 - had an organ transplant, such as a kidney transplant.
 - have liver damage from diseases or drugs.
 - have any other medical conditions.
- It is very important to tell your doctor immediately if you have, or develop, any of the symptoms listed under **Serious Side Effects. Do not try to treat or diagnose symptoms yourself.**
- You may have a **transient worsening of disease** before the tumour shrinks.
- Avelumab may damage sperm and may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with avelumab and for at least **one month** after the last dose. Tell your doctor right away if you or your partner becomes pregnant.
- Avelumab may pass into your breast milk. **Do not breastfeed** during treatment and for at least **1 month** after the last dose.
- **Tell** doctors or dentists that you are being treated with avelumab before you receive any treatment from them. You should carry the BC Cancer **wallet card** for checkpoint inhibitor to alert health providers.
- **Do not receive any immunizations before discussing with your doctor**

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Avelumab may cause serious immune reactions against your own body (autoimmune) affecting many parts.

Are there any risks?

Unexpected and unlikely side effects can occur with any drug treatment. The ones listed below are particularly important for you to be aware of as they are directly related to the common actions of the drugs in your treatment plan.

What is the most important information I should know about SERIOUS SIDE EFFECTS?

- Avelumab can cause serious side effects in many parts of your body. These side effects are most likely to begin during treatment; however, side effects can show up months after your last treatment.
- **Tell** your doctor as soon as possible if you have any of serious side effects listed in the table below or your symptoms get worse.
- **Do not try to treat or diagnose symptoms yourself.** Getting medical treatment right away may keep the problem from becoming more serious.

The following side effects were most frequently reported:

Very common (more than 1 in 10 people)

- Itching
- High blood pressure
- Headache
- Joint pain

Common (may affect up to 1 in 10 people)

- Allergic reaction to the drug, increased tendency of body to have allergic reactions
- Redness of the skin
- Increase liver enzymes in the blood
- Increase thyroid hormone in the blood

SERIOUS SIDE EFFECTS	How common is it?
<p>Infusion reaction. <i>Symptoms may include</i></p> <ul style="list-style-type: none"> • shortness of breath, wheezing or trouble breathing, cough, chest tightness • dizziness, fainting, rapid or weak heartbeat • itching, rash, hives, or feeling warm or flushed • swelling of the throat, tongue, or face • hoarse voice, throat tightness or trouble swallowing 	<p>Very Common (more than 1 in 10)</p>
<p>Problems with MUSCLES <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • back pain • spasms • weakness • muscle or joint pain 	<p>Very Common (more than 1 in 10)</p>
<p>Inflammation of the NERVES <i>Symptoms may include</i></p> <ul style="list-style-type: none"> • weakness of legs, arms or face • numbness or tingling in hands or feet • lack of energy or dizziness 	<p>Very Common (more than 1 in 10)</p>
<p>Problems in the PANCREAS <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • abdominal pain • nausea and vomiting 	<p>Very Common (more than 1 in 10)</p>
<p>Inflammation of the SKIN <i>Symptoms may include</i></p> <ul style="list-style-type: none"> • rash on your skin, mouth blisters, dry or peeling skin • itchy skin 	<p>Common (less than 1 in 10 but more than 1 in 100)</p>

SERIOUS SIDE EFFECTS	How common is it?
<p>Inflammation of the INTESTINES (colitis) <i>Symptoms may include</i></p> <ul style="list-style-type: none"> • diarrhea (loose stools) or more bowel movements than usual. Do not treat the diarrhea yourself. • blood in stools or dark, tarry, sticky stools • stomach pain (abdominal pain) or tenderness • fever 	<p>Common</p> <p>(less than 1 in 10 but more than 1 in 100)</p>
<p>Inflammation of the THYROID GLAND (hyperthyroidism, hypothyroidism) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • rapid heart beat • weight loss or gain • increased sweating • hair loss • feeling cold • constipation or diarrhea • your voice gets deeper • muscle aches • changes in sleep patterns 	<p>Common</p> <p>(less than 1 in 10 but more than 1 in 100)</p>
<p>Inflammation of the LUNGS (pneumonitis) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • shortness of breath • chest pain • coughing 	<p>Common</p> <p>(less than 1 in 10 but more than 1 in 100)</p>

SERIOUS SIDE EFFECTS	How common is it?
<p>Inflammation of the LIVER (hepatitis) <i>Symptoms may include</i></p> <ul style="list-style-type: none"> • yellowing of your skin or the whites of your eyes, • dark urine, tiredness, nausea or vomiting, loss of appetite, pain on the right side of your stomach, or bruise easily 	<p>Common (less than 1 in 10 but more than 1 in 100)</p>
<p>Inflammation of certain GLANDS (pituitary, adrenal glands) so they do not make enough hormone. <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • weight loss • increased sweating, hot flashes • hair loss (includes facial and pubic) • feeling cold • headaches that will not go away or unusual headache • changes in behavior such as less sex drive, being irritable or forgetful • vision problems, dizziness or fainting • excessive thirst and urination • unusual tiredness or sleepiness 	<p>Uncommon (less than 1 in 100)</p>
<p>Inflammation of the EYES <i>Symptoms may include</i></p> <ul style="list-style-type: none"> • changes in eyesight, blurry vision, double vision, or other vision problems • eye pain or redness 	<p>Uncommon (less than 1 in 100)</p>
<p>Inflammation of the KIDNEYS (nephritis) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • changes in the amount or colour of your urine 	<p>Uncommon (less than 1 in 100)</p>

SERIOUS SIDE EFFECTS	How common is it?
<p>Blood sugar problems (type 1 diabetes mellitus) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • hunger or thirst • a need to urinate more often • weight loss • increase in blood sugar 	<p>Uncommon (less than 1 in 100)</p>

OTHER SIDE EFFECTS	MANAGEMENT
<p>Pain or tenderness may occur where the needle was placed.</p>	<p>Apply cool compresses or soak in cool water for 15-20 minutes several times a day.</p>
<p>Your white blood cells may decrease after your treatment. White blood cells protect your body by fighting bacteria (germs) that cause infection. When they are low, you are at greater risk of having an infection.</p>	<p>To help prevent infection:</p> <ul style="list-style-type: none"> • Wash your hands often and always after using the bathroom. • Avoid crowds and people who are sick. • Call your doctor immediately at the first sign of an infection such as fever (over 100°F or 38°C by an oral thermometer), chills, cough, or burning when you pass urine.
<p>Your platelets may decrease after your treatment. Platelets help to make your blood clot when you hurt yourself. You may bruise or bleed more easily than usual.</p>	<p>To help prevent bleeding problems:</p> <ul style="list-style-type: none"> • Try not to bruise, cut, or burn yourself. • Clean your nose by blowing gently. Do not pick your nose. • Avoid constipation. • Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Maintain good oral hygiene. <p>Some medications such as ASA (e.g., ASPIRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding.</p> <ul style="list-style-type: none"> • Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart). • For minor pain, try acetaminophen (e.g., TYLENOL®) first, to a maximum of 4 g (4000 mg) per day, but occasional use of ibuprofen may be acceptable.

OTHER SIDE EFFECTS	MANAGEMENT
Diarrhea may sometimes occur.	<i>Immediately</i> see your doctor or get emergency help.
Constipation may sometimes occur.	See or call your doctor as soon as possible.
Nausea and vomiting may occur after your treatment. Most people have little or no nausea.	
Headache may sometimes occur.	
Swelling of hands, feet, or lower legs may sometimes occur if your body retains extra fluid.	
Hair loss does not occur with avelumab.	

If you experience symptoms or changes in your body that have not been described above but worry you, or if any symptoms are severe, contact:

_____ at telephone number: _____



Provincial Health Services Authority

MEDICAL ALERT

NAME _____

has received

CHECKPOINT INHIBITOR IMMUNOTHERAPY:

Immune-Mediated Adverse Reactions

ALWAYS CARRY THIS CARD AND SHOW TO PHYSICIANS INCLUDING ANESTHETISTS

SEVERE IMMUNE-MEDIATED ADVERSE REACTIONS
Including enterocolitis, intestinal perforation, hepatitis, dermatitis (including toxic epidermal necrolysis), neuropathy, endocrinopathy, pneumonitis, myositis, myocarditis and toxicities in other organ systems. Duration of risk after treatment is unknown.

FOR MORE INFORMATION:

- BC Cancer - Abbotsford604-851-4710
- BC Cancer - Kelowna250-712-3900
- BC Cancer - Prince George.....250-645-7300
- BC Cancer - Surrey604-930-4055
- BC Cancer - Vancouver.....604-877-6000
- BC Cancer - Victoria.....250-519-5500

www.bccancer.bc.ca/health-professionals/professional-resources/cancer-drug-manual

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To Whom It May Concern:

RE: _____

Medical Oncologist _____

Immunotherapy Regimen _____

This patient is receiving **immunotherapy** at the BC Cancer and is at risk of **immune-related toxicities** which may be life threatening and require urgent management.

Immunotherapy toxicities are different from those encountered with standard chemotherapy or targeted therapies. The immune system may become dysregulated during immunotherapy treatment, leading to symptoms and findings which mimic autoimmune disorders. Adverse events can occur during or following treatment and can be life threatening. Any organ system in the body is at risk including, but not limited to:

- Lungs (pneumonitis, pleuritis, sarcoidosis)
- Gastrointestinal (colitis, ileitis, pancreatitis)
- Liver (hepatitis)
- Skin (rash, Stevens-Johnson syndrome)
- Endocrine (hypophysitis, adrenal insufficiency, hypo/hyperthyroidism, type 1 diabetes mellitus)
- Renal (interstitial nephritis)
- Blood (hemolytic anemia, thrombocytopenia, neutropenia)
- Neurologic (encephalitis, Guillain-Barré syndrome, meningitis, myasthenia gravis, neuropathy)
- Musculoskeletal (myositis, arthritis)
- Cardiovascular (pericarditis, myocarditis, vasculitis)
- Ophthalmologic (uveitis, scleritis, episcleritis, conjunctivitis, retinitis)

Management of immune-related toxicities necessitates prompt coordination with a medical oncologist with **initiation of high dose corticosteroids**, and may require referral to the appropriate subspecialty. If you suspect your patient is presenting with immune-related toxicity, **please contact the patient's medical oncologist** directly or if after hours contact the on-call physician, or as per your local centre's process (next page). Additional information on immunotherapy toxicity treatment algorithms is located at the end of the above posted protocol at www.bccancer.bc.ca.

BC CANCER CENTRES	CONTACT INFORMATION AND PROCESS
Abbotsford	Contact the patient's medical oncologist immediately by calling the Abbotsford Regional Hospital and Cancer Centre (ARHCC) switchboard at (604) 851-4700 and ask for the on-call medical oncologist (24-hour call system).
Kelowna	Between 8:30 am – 5:00 pm, call (250) 712-3900 (press "8" to speak to the Kelowna Centre receptionist) and have an oncologist paged. Outside these hours, call the Kelowna General Hospital switchboard at (250) 862-4000 and ask for the on-call medical oncologist.
Prince George	Between 8:30 am – 4:00 pm Monday to Friday, call (250) 645-7313. Outside these hours, go to the emergency department at the University Hospital of Northern British Columbia (UHNBC).
Surrey	Between 8:30 am – 4:00 pm Monday to Friday (except Statutory holidays), call the Nursing Phone Line at (604) 930-4053. Outside these hours, call the Surrey Memorial Hospital switchboard at (604) 581-2211 and ask for the Fraser Valley on-call medical oncologist.
Vancouver	Between 8:30 am – 4:30 pm Monday to Friday, call the Patient Nurse Line at (604) 877-6025. Outside these hours, call the inpatient unit at (604) 877-6000 and press 1, and ask for the on-call medical oncologist.
Victoria	Between 8:30 am – 4:30 pm Monday-Friday (except Statutory holidays), call (250) 519-5500, and press 1 then 4 to speak with a registered nurse. Outside these hours, call the Royal Jubilee Hospital switchboard at (250) 370-8000 and ask for the on-call medical oncologist.